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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,861	02/23/2004	Gilbert S. Laroya	002-C1	9437

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
05/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/784,861	LAROYA ET AL.	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-22 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-22 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on February 4, 2010. Examiner acknowledges the amendment of claims 1, 8, 9, 16, 17 and 19-21; the cancellation of claims 18 and 23-32; and the addition of new claim 33. Claims 1-17, 19-22 and 33 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 8, 9, 13, 16, 17, 20-22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al. (U.S. Patent Number 5,715,818) in view of Knudson et al. (U.S. Patent Number 6,093,166).

In regard to claims 1, 2, 8, 9, 13, 16, 17, 20-22 and 33, Swartz et al. disclose a system for placing a guide member through the wall and into the left atrium of the patient's heart (Abstract; col. 1, lines 63-67; col. 2, lines 1-30). The system comprises an introducer that can be sized and configured for placement through a coronary vessel and the wall of a patient's heart into a heart chamber and a guide member which can be sized and configured to be positioned in the introducer and placed through the coronary vessel and the heart wall into the heart chamber (Figure 2).

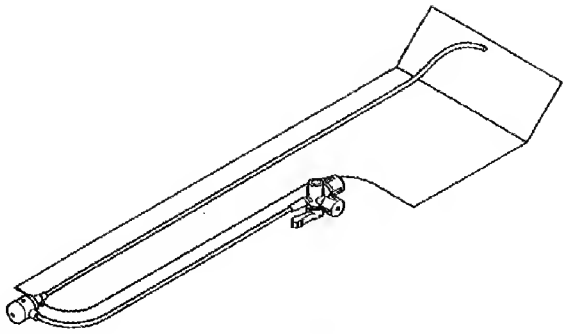
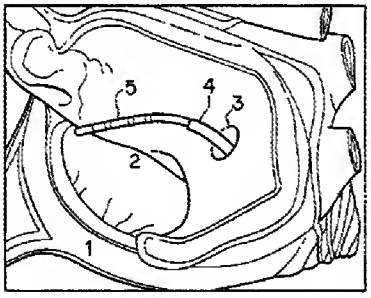


FIG. 4

The guide member disclosed by Swartz et al. has a proximal portion adapted to remain outside the heart and a distal portion adapted to be passed into and then back out of the heart chamber. As the guide member of the Swartz et al. device is passed through the introducer and moves through the coronary vessel and the heart wall to a location within the heart chamber. Figure 4 shows the device and the controller mechanism which is located at the proximal portion of the device. The introducer is a hollow sleeve which receives a guide wire. Swartz discloses passing the distal end of the guide wire through the introducer into the heart chamber (Figure 2).

SHEATH & CATHETER
IN
LEFT ATRIUM



1. CORONARY SINUS
2. MITRAL VALVE
3. FOSSA OVALIS (PATENT)
4. SHEATH
5. CATHETER

FIG. 2

Swartz et al. discloses the introducer of the system and the guide member can be configured to direct the distal portion of the guide member to a predetermined location within the heart chamber upon introducing the guide member into the chamber (col. 7, lines 17-45). The guide member is configured for delivery to an internal surface of the left atrium as disclosed by Swartz et al. Upon use of the Swartz et al. system, the device is placed in a patient's heart extending the guide wire through a coronary vessel (col. 6, lines 34-67; col. 7, lines 1-16). The guide wire is further extended into a heart chamber containing blood and then passed back out the heart chamber (col. 3, lines 44-67; col. 6, lines 8-62). In regard to the claims, Swartz discloses the features of the Applicant's invention as described above. Although Swartz is capable of performing such a procedure, Swartz does not specifically disclose the introducer being provided through a coronary vessel and extending into and out of a blood vessel through openings of the vessel wall or through an opening of a heart wall into a heart chamber. Knudson discloses a coronary bypass implant which includes a method and apparatus foe performing coronary artery bypass surgery to establish a channel leading directly from a heart into a coronary artery. Knudson et al. further disclose gaining access to the left ventricle for this procedure. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a system for placing a guide member through the wall of a patient's heart so that the guide member can extend through a coronary vessel and the wall of the heart, similar to that disclosed by Swartz et al., to include a method and apparatus for performing coronary artery bypass surgery to establish a channel leading directly from a heart into a coronary artery, similar to that disclosed by Knudson et al., to provide a fluid communication channel through a

coronary vessel and the vessel wall or through an opening of a heart wall into a heart chamber.

4. Claims 3-7, 10-12, 14, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al. (U.S. Patent Number 5,715,818)) in view of Knudson et al. (U.S. Patent Number 6,093,166) and in further view of Cope et al. (U.S. Patent Number 5,776,079).

In regard to claims 3-7, 10-12, 14, 15 and 19, the combined references of Swartz et al. and Knudson et al. disclose the features of the Applicant's invention as described above. The combination does not disclose having a snare device adapted to grasp and pull the guide member out of the heart chamber. Cope et al. discloses a catheterization apparatus including a catheter which introduces a guide wire into a vessel. The apparatus further includes an inserter sheath engageable with the catheter to facilitate the passage of the guide wire through the catheter (Abstract). Cope et al. also disclose the use of a balloon catheter for accessing a vasculature site of interest. Once the apparatus is introduced into a vessel, Cope et al. teach the use of a snare device in conjunction with the apparatus to remove the apparatus from the vessel in which it is deployed. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a system and method for using a guiding introducer, similar to that disclosed by Swartz et al. and Knudson et al., to include a snare device to retrieve the guide member, similar to that disclosed by Cope et al., to provide a mechanism which retrieves the device upon adverse events occurring during use which may lead to problems for the patient (col. 8, lines 58-67; col. 9, lines 1-18).

Response to Arguments

5. Applicant argues the prior art references applied in outstanding office action do not teach an introducer being provided through a coronary vessel and extending into and out of a blood vessel through openings of the vessel wall or through an opening of a heart wall into a heart chamber. Examiner submits the combined references which include the teachings of Knudson et al. teach a device is capable of meeting claim limitations as amended. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-17, 19-22 and 33 are rejected on the ground of nonstatutory double patenting over claims 1-6, 8-16, 18-21 and 31 of U. S. Patent No. 6,808,498 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

a. Claims 1, 3, 7-9 and 15 of Applicant's invention and Claims 8 and 9 of the patent both claim a system for placing a guide member through the wall of a patient's heart such that the guide member extends through a coronary vessel and the wall of the heart into a heart chamber with the system comprising an introducer, a guide member and a conduit sized and configured for placement in the wall of the heart.

b. Claim 2 of Applicant's invention and Claim 2 of the patent both disclose the details of the system including the introducer being a hollow sleeve, the guide

member being a guide wire and the distal portion of the guide wire including a distal end that is passed through the introducer.

c. Claim 4 of Applicant's invention and Claim 3 of the patent both claim a system wherein the device is a snare adapted to grasp the guide member and pull the guide member out of the heart chamber.

d. Claim 5 of Applicant's invention and Claim 4 of the patent both claim a system wherein the distal portion of the guide member is configured to be carried out of the heart chamber by blood flowing out of the heart chamber.

e. Claims 6 and 7 of Applicant's invention and Claims 5 and 6 of the patent both disclose the distal portion of the guide member supporting a balloon that is engaged by blood flowing out of the heart chamber and the guide wire coupled to a catheter supporting the balloon; the balloon functioning to pull the catheter and guide wire into the heart chamber.

f. Claims 10-14 of Applicant's invention and Claims 10-14 of the patent both claim a system for delivering a conduit into the wall of a patient's heart to communicate a coronary vessel with a heart chamber with the system comprising an introducer, a guide wire guiding member coupled to a conduit, and the conduit sized and configured for placement in the wall of the heart; the conduit being supported by a delivery device which has a clamp for locking the device to the guide wire.

g. Claims 16 and 17 of Applicant's invention and Claims 15 and 16 of the patent both claim a method for placing a guide member in a patient's heart so that the guide member extends through a coronary vessel and the wall of the heart into a

heart chamber with the method comprising steps of passing a first end of a guide member through the coronary vessel and through the wall of the heart to allow the guide member to pass through a heart chamber containing blood; maintaining a second end of the guide member outside of the heart chamber and passing the first end of the guide member back out of the heart chamber; and delivering a conduit to the heart wall.

h. Claims 19-22 of Applicant's invention and Claims 18-21 of the patent both disclose a method which includes steps of introducing a snare through the heart wall into the heart chamber and grasping the guide member to remove the first end of the guide member, where the first end of the guide member is configured to be forced out of the left ventricle heart chamber and into the aorta by blood flow and the guide member is further used to deliver a tissue removal device into the heart chamber.

i. Claim 33 of Applicant's invention and Claim 31 of the patent both disclose a method which includes positioning a conduit in the heart wall to establish a fluid communication between the heart chamber and the interior of the coronary vessel wherein the conduit is left in place after removing the guide member.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

/Fangemonique Smith/

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736